IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION MDL No. 2187

THIS DOCUMENT RELATES TO C. R. BARD WAVE 4 & WAVE 5 CASES BEFORE JUDGE GOODWIN:

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Joseph Maccarone, M.D.)

The plaintiffs filed their Notice of Adoption of Prior Daubert Motion of Joseph Maccarone, M.D. for Waves 4 and 5 Cases ("Notice") [ECF No. 4544] in *In re C. R. Bard, Inc.*, *2:10-md-2187*, MDL 2187, on September 27, 2017. The plaintiffs attached as exhibits to their Notice a motion [ECF No. 4544-1], memorandum in support [ECF No. 4544-2], and reply brief [ECF 4544-3], which plaintiffs seek to adopt and incorporate as their briefing for Waves 4 and 5. Defendant also adopted and incorporated by Notice of Adoption of C.R. Bard, Inc.'s Prior Memorandum of Law in Opposition to Plaintiffs' Motion to Exclude Testimony of Joseph Maccarone, M.D., for Wave 4 and Wave 5 cases, a brief in response to the plaintiffs' Motion. [ECF No. 4642]. The court construes the plaintiffs' Notice as a motion. As such, the Notice is now ripe for consideration because the briefing is complete. As set forth below, the plaintiffs' motion is **GRANTED in-part** and **DENIED in-part**.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 16,000 cases currently pending, approximately 1,500 of which are in the Bard MDL, 2187 MDL.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict Litigation in Products Liability Cases* 3 (2011). In an effort to manage the massive Bard MDL efficiently and effectively, the court decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a "wave" of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, a docket control order subjects each case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order ("PTO") # 236 (establishing Wave 4); PTO # 244 (establishing Wave 5). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure for cases designated in Wave 4 and Wave 5. The court instructed the parties to file briefing on general causation issues in the main MDL, MDL 2187, while specific causation *Daubert* motions, responses,

and replies were to be filed in the individual member cases. To the extent that an expert is both a general and specific causation expert, the court advised the parties that they could file a general causation motion in the main MDL and a specific causation motion in an individual member case. *See* PTO # 236, at 4; PTO # 244, at 4.

Before plunging into the heart of the motion, and to clarify the record, I am compelled to comment on the manner in which the parties filed the instant *Daubert* motion and response in opposition. Similar to other *Dauberts* filed in the main MDL, the plaintiffs filed the instant motion as a "Notice," adopting and incorporating the entirety of a motion and its corresponding papers filed in a previous case before the court. Defendant C. R. Bard, Inc. ("Bard"), likewise, filed its opposing briefs in conjunction with a similar "Notice." The parties then attached the substance of their briefs, i.e., the supporting or opposing memorandum of law, as an exhibit to their respective Notice. So, for example, the plaintiffs attach the memorandum in support of their *Daubert* motion as "Exhibit 1" to their Notice. The plaintiffs also integrate into Exhibit 1 vital supporting papers, such as the expert report and deposition transcripts, forming one large and continuous document. With this in mind, the court turns its attention to the present dispute.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and (1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles

and methods" which (3) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to "prove" anything. However, he or she must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court is the gatekeeper. It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading"; the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I "need not determine that the proffered expert testimony is irrefutable or certainly correct" – "[a]s with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (quoting *Daubert*, 509 U.S. at 596 (alteration in original)); *see also Md. Cas. Co.*, 137 F.3d at 783 ("All *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful.").

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the

particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'" (citation omitted)); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted). At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

III. Discussion

Bard offers Dr. Joseph Maccarone, board-certified in OB/GYN and female pelvic surgery, to testify on a number of general causation issues, including the characteristics of mesh after implantation, the human body's response to polypropylene mesh, and the adequacy of Bard's warning. The plaintiffs seek to exclude Dr. Maccarone from testifying on a number of topics, which the court will address in turn.

A. Opinions on the Characteristics of Polypropylene Mesh After Implantation

First, the plaintiffs argue that Dr. Maccarone is not qualified to opine on how the mesh product reacts in the human body because he has explanted only two mesh products in his twenty-one years of practice. *See* Notice of Adoption of Prior Daubert Mot. of Joseph Maccarone, M.D., for Waves 4 & 5 Cases, Ex. 1 ("Pls.' Mem. in Supp."), at 5 [ECF No. 4544-1]. I disagree.

The mere absence of extensive clinical experience with explanted mesh alone does not render a surgical obstetrician unqualified to testify on how polypropylene mesh functions once implanted. Clearly, Dr. Maccarone has extensive clinical and academic experience in the relevant specialty. He performs approximately one hundred pelvic reconstructive surgical cases yearly, including fifty to sixty synthetic multi-incision sling procedures to treat female stress urinary incontinence a year.

Having implanted materials "on a weekly basis" the court is satisfied with Dr. Maccarone's qualifications. *See* Notice of Adoption of Def.'s Prior Mem. of Law in Opp'n to Pls.' Daubert Mot. to Exclude the Test. of Joseph Maccarone, M.D., for Wave 4 & 5 Cases, Ex. B ("Def.'s Mem. in Opp'n"), at 3–4 [ECF No. 4642-2].

Therefore, I **FIND** Dr. Maccarone qualified to opine on how polypropylene mesh functions once implanted.

Next, the plaintiffs assert that Dr. Maccarone cherry picked supporting literature and discounted, without a rational basis, discrediting reports. As a result, the plaintiffs claim that Dr. Maccarone's opinion is unreliable.

An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead "selectively [chooses] his support from the scientific landscape." *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005) (quotations omitted). "[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable." *Id.*; *see also Abarca v. Franklin Cnty. Water Dist.*, 761 F. Supp. 2d 1007, 1066 n.60 (E.D. Cal. 2011) ("A scientist might well pick data from many different sources to serve as circumstantial evidence for a particular hypothesis, but a reliable expert would not ignore contrary data, misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted." (quotations omitted)); R*imbert v. Eli Lilly & Co.*, CIV 06–0874 JCH/LFG, 2009 WL 2208570, at *14 n.19 (D.N.M. July 21, 2009) *aff'd*, 647 F.3d 1247 (10th Cir. 2011) ("[A]n expert who chooses to completely ignore

significant contrary epidemiological evidence in favor of focusing solely on non-epidemiological studies that support her conclusion engages in a methodology that courts find unreliable.").

Here, the plaintiffs' do not allege that Dr. Maccarone completely ignored significant contrary evidence in the relevant scientific literature directly, but instead challenge his reasons for discounting such studies. According to the plaintiffs, his explanations are arbitrary, illogical, and inconsistent.

Whether Dr. Maccarone's reasons for rejecting certain studies are accurate or whether Dr. Maccarone inconsistently applies these reasons to the literature are appropriate topics for cross-examination. *See In re Actos (Pioglitazone) Prods. Liab. Litig.*, No. 12–cv–00064, 2014 WL 60324, at *8 (W.D. La. Jan. 7, 2014) (stating that "an expert can and does exercise his or her judgment and if he or she gives reasons for that decision and full explanation for those choices, disagreement with those choices becomes a matter for the trier of fact"). Therefore, the plaintiffs' motion on this point is **DENIED**.

B. Opinions Regarding Design Defects

In his expert report, Dr. Maccarone asserts that the Align slings manufactured by Bard "do not have any defects in design." Mot. of Joseph Maccarone, M.D., for Waves 4 & 5 Cases, Ex. 1 ("Dr. Maccarone's Expert Report"), at 9 [ECF No. 4544-1]. The plaintiffs challenge the reliability of this opinion on grounds that he bases this opinion entirely on his personal unscientific observations as a practicing gynecologist:

> Q: And you state that Bard Align slings do not have defects in design. What evidence do you have to support that?

> A: Well, my own personal clinical experience implanting these devices. I've seen no problems, no issues related to the trocars, the introducers, sheath, the pull tab, the ability to deliver the material and keep it flat. I've had absolutely no problems at all. I've never explanted one. So based on my own personal opinion, it functions as designed as a treatment for female stress incontinence.

Pls.' Mem. in Supp., at 8.

In response, Bard contends that Dr. Maccarone's opinion based on his clinical observations is scientific and further supported by a body of literature identifying these products as the "gold standard." Def.'s Mem. in Opp'n, at 8. Notably absent from Dr. Maccarone's expert report, however, is any explanatory correlation between the "gold standard" literature Bard identifies in support and the specifics of manufacturing a mesh product. In doing so, Dr. Maccarone relies entirely upon his own clinical observations that nothing adverse concerning the product has occurred, and therefore the product itself must be properly designed. Regardless of the experience he has gained in his clinical practice, a necessary piece of data remains missing from Dr. Maccarone's methodology that results in a speculative leap, which is improper for expert testimony. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."); *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999) (finding that *Daubert* bars expert testimony based on "belief or speculation").

Accordingly, Dr. Maccarone may not rely solely on his general clinical observations to support his opinion regarding the propriety of the mesh product's design. The plaintiffs' motion on this point is **GRANTED**.

C. Factors Responsible for Adverse Events and Opinions Regarding the Inflammatory Response

The plaintiffs also assert that Dr. Maccarone again relied upon his clinical observations alone when forming his opinion that an inflammatory response six months after surgery cannot "exist," and that "operator inexperience, lack of technical competency, and the normal risks of surgery—not problems with material or design—are the factors responsible for any adverse patient outcomes." Pls. Mem. in Supp., at 9. While "no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience," *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 156 (1999), when an expert is relying "solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." Fed. R. Evid. 702 advisory committee's note to 2000 amendment.

Having failed to do so, and for the same reasons articulated above, this opinion appears more speculative than scientific, and the plaintiffs' motion on this point is **GRANTED**.

D. Opinions Regarding the Material Safety Data Sheet ("MSDS")

The plaintiffs seek to prevent Dr. Maccarone from testifying on the utility and interpretation of language contained in the MSDS corresponding to the polypropylene resin used in the manufacture of the mesh products in question. Specifically, Dr. Maccarone opines that he has not seen "evidence that there is any scientific basis supporting the medical application caution language in the MSDS" and that the

"cautionary statement about human implantation and the company's lack of responsibility for human use is out of place in a document clearly devoted to work place safety, and does not jibe with the scope and purpose of the MSDS." Pls. Mem. in Supp., at 10 (citing Dr. Maccarone's Expert Report, at 6).

In doing so, Dr. Maccarone, who has no knowledge about a manufacturer's considerations when drafting an MSDS, attempts to opine that because he did not see any evidence suggesting the MSDS has scientific roots, none exists. Such a speculative leap is improper for expert testimony. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."). Therefore, the plaintiffs' motion on this point is **GRANTED**, and this opinion is **EXCLUDED**.

IV. Conclusion

For the reasons stated above, the court **ORDERS** that the plaintiffs' Notice of Adoption of Prior Daubert Motion of Joseph Maccarone, M.D. for Waves 4 and 5 Cases [ECF No. 4544], which the court has construed as a motion, is **GRANTED in part** and **DENIED in part.**

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:10-md-2187, and the Bard Wave 4 and Wave 5 cases identified in the Exhibit attached hereto. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: September 5, 2018

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

Exhibit A

CIVIL ACTION NUMBER	Case Name
2:14-cv-03439	Kitchen v. C. R. Bard, Inc. et al.
2:14-cv-18890	McManus v. C. R. Bard, Inc. et al.
2:14-cv-21874	McCray v. C. R. Bard, Inc. et al.
2:14-cv-23401	Barber v. C. R. Bard, Inc. et al.
2:14-cv-28943	Smith et al. v. C. R. Bard, Inc. et al.
2:16-cv-01855	Eiffler v. Sofradim Production SAS et al.